UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re INTUNIV ANTITRUST LITIGATION	Civil Action Nos. 16-cv-12653-ADB (Lead) 17-cv-10050-ADB (Consol.)
	CLASS ACTION
This Document Relates to: Direct Purchaser Actions	JURY TRIAL DEMANDED
	REDACTED VERSION

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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The plaintiff FWK Holdings, LLC, on behalf of itself and all others similarly situated, for its class action complaint against (1) Shire LLC, and Shire U.S., Inc. (collectively, "Shire") and (2) Actavis Elizabeth LLC, Actavis Holdco US, Inc. and Actavis LLC (collectively "Actavis"), allege, based on personal knowledge as to itself and upon information and belief as to the other allegations, as follows:

I. INTRODUCTION

1. This case arises from an illegal reverse payment agreement in the market for the attention-deficit/hyperactivity disorder (ADHD) drug Intuniv. Intuniv manufacturer Shire and generic manufacturer Actavis colluded to keep generic Intuniv off the market for over a year and a half in order to prolong Shire's monopoly profits, and share some of those profits with Actavis.

2. In April 2013, Shire and Actavis entered into a reverse payment agreement under which Actavis agreed to delay the entry of its ANDA-approved generic Intuniv until December 1, 2014, and, in return, Shire ensured that no authorized generic would compete against Actavis's generic Intuniv during Actavis's 180-day exclusivity period, an agreement worth over $424 million in sales to Shire and approximately $53 million in profits to Actavis as compared to what they would have earned under competitive conditions. Were it not for the deal between Shire and Actavis (a payoff that kept generic Intuniv off the market for over a year and a half, and then made Actavis's generic Intuniv the only generic on the market for 180 days), American purchasers of Intuniv would have saved an estimated one-half billion dollars.

3. This is a civil antitrust action seeking treble damages arising out of the defendants' unlawful impairment of competition for the drug Intuniv. Shire and Actavis collaborated in an unlawful reverse payment agreement to block generic competition in order to share monopoly profits between themselves and, thereby, harm consumers.

4. Intuniv is the Shire brand name for an extended-release tablet form of guanfacine, approved by the FDA on September 2, 2009 – a prescription medication for the treatment of ADHD in children and adolescents. In 2013, Intuniv had U.S. market sales of $335 million. Hundreds of thousands of parents have depended on Intuniv for the treatment of ADHD in their children.

5. The patent and drug regulation laws afforded Shire a period during which no manufacturer could sell a generic version of Intuniv. Until the Hatch-Waxman Act's three-year exclusivity period on Intuniv expired on September 2, 2012, Shire legally occupied 100% of the Intuniv market, charged supra-competitive prices, and earned monopoly profits.

6. When this exclusivity period expired, generic manufacturers would be able to obtain FDA approval to market equivalent, but much less expensive, generic versions of the drug. A significantly cheaper, medically equivalent, generic version of Intuniv would quickly take over the market. Indeed, in certain states, a pharmacist is required to provide patients with the generic, unless the patient requests the brand drug, or the doctor specifically indicates that the patient must receive the brand drug. Shire's monopoly on Intuniv, along with the supracompetitive profits derived from it, would disappear once generic competitors entered the market in September 2012.

7. Facing this imminent and certain erosion of brand sales, Shire engaged in a scheme to block generic competition by effectively paying generic drug manufacturer Actavis to delay its market entry until December 1, 2014, and thereby block other generic entrants until June 2015. Absent Shire's agreement with Actavis, and Actavis's expectation and knowledge that such a deal was in the offing, Actavis would have entered the market possibly as early as October 5, 2012, and almost certainly no later than in May 2013.

8. On December 29, 2009, Actavis filed the first Abbreviated New Drug Application (ANDA) seeking FDA approval for generic Intuniv. Actavis argued that all three of Shire's patents on Intuniv were either invalid or not infringed. As the first generic filer, Actavis was potentially entitled to a 180-days period during which other generic manufacturers would not be allowed to sell generic Intuniv (aside from an Intuniv "authorized generic" sold by Shire).

9. Following Actavis's ANDA, other generic manufacturers also filed ANDAs for Intuniv: Teva Pharmaceuticals USA, Inc. on January 25, 2010; Anchen Pharmaceuticals, Inc. ("Anchen") on January 28, 2010; Mylan Pharmaceuticals, Inc. ("Mylan") on November 30, 2010; and Sandoz, Inc. ("Sandoz") on December 28, 2010. Anchen later transferred its ANDA to TWi Pharmaceuticals ("TWi").

10. Shire filed lawsuits in the District of Delaware and elsewhere against the generic manufacturers, alleging infringement of the patents purportedly covering Intuniv. Shire sued Teva on April 22, 2010,[1] followed by Actavis on May 12, 2010,[2] and Anchen on June 2, 2010.[3] The lawsuits triggered a 30-month stay under applicable law so that the ANDAs could not be approved for 30 months (from the date each generic manufacturer gave notice to Shire) while the lawsuits were pending, unless they were resolved in favor of the generic manufacturer. Unless the generic manufacturers prevailed in the patent cases, the FDA could not approve Actavis's ANDA until October 5, 2012, and could not approve any other ANDA until Actavis's 180-day exclusivity lapsed or expired.

[1] *Shire LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 10-329 (D. Del.)

[2] *Shire LLC, et al. v. Actavis Elizabeth LLC, et al.*, No. 10-397 (D. Del.)

[3] *Shire LLC, et al. v. Anchen Pharmaceuticals Inc., et al.*, No. 10-484 (D. Del.)

11. On September 4, 2012, Shire settled its patent cases with TWi and Anchen. The settlement provided: (a) Anchen could launch a generic Intuniv on July 1, 2016, or earlier under certain circumstances, such as [redacted]

12. From September 17 through 20, 2012, a bench trial was held on Shire's claims against Actavis and Teva for infringement of two of Shire's Intuniv patents. The court did not render a decision at that time.

13. On October 5, 2012, Actavis's 30-month stay expired, and on that same day, Actavis received final approval of its ANDA. Actavis's timely approval locked in its first-to-file, 180-day exclusivity period: i.e., when it launched its generic Intuniv, it would be guaranteed 180 days free from competition from the other ANDA filers.

14. On April 25, 2013, Shire and Actavis settled their lawsuit in a settlement and license agreement containing a reverse payment from Shire to Actavis. Although Actavis had final FDA approval to launch its generic Intuniv, Actavis agreed in the settlement that it would delay launch of its ANDA-approved generic Intuniv for over a year and a half, until December 1, 2014. In exchange for this delay, Shire agreed that, upon Actavis's eventual launch of a generic, Shire would not release an authorized generic ("AG") during Actavis's 180-day exclusivity period. The agreements disguised the no-AG agreement – [redacted]

[redacted] But this latter provision, given the economic and regulatory realities, was known to be a false possibility, rendering the agreement to function as a routine no-AG deal (with only the thinly veiled pretext intended to be used to avoid antitrust scrutiny).

15. Shire and Actavis knew that Actavis's profits during the 180-day exclusivity period would be vastly increased in a market without an authorized generic, so much so that the agreements included an obligation of Actavis to pay back to Shire a 25% "royalty" on gross profits earned during the exclusive, no-AG period. The "royalty" added an incentive for Shire not to launch its own (i.e., non-third party) AG, yet ensured that Actavis would still make a significant additional profit, inducing it to enter into the deal and delay its generic entry. The arrangement resulted in (i) Shire maintaining its Intuniv monopoly, without generic competition, through December 1, 2014, and (ii) Actavis enjoying a 180-day exclusivity period during which it would not face competition from any other generic, including Shire's authorized generic.

16. In the absence of this settlement agreement, a reasonable generic company in Actavis's position was likely to prevail in the patent litigation, and would have launched a generic Intuniv immediately thereafter, most likely in May 2013. The circumstances also warrant the inference that a reasonable generic company in Actavis's position would have launched as early as October 5, 2012, right after obtaining FDA approval of its ANDA, believing that its chance to prevail in the patent litigation was high enough that it was willing to launch "at risk" – to risk patent liability by launching its product while patent litigation was still ongoing.

17. With a reasonable generic company in Actavis's position entering the market earlier, a reasonable brand company in Shire's position would have launched an authorized

generic during that 180-day period (likely with Anchen and another third party as its distributors). Instead, Shire obtained a longer period of Intuniv brand exclusivity through December 2014 without generic competition.

18. Shire's agreement with Actavis was a collusive agreement to maintain a monopoly market. Shire's promise that no authorized generic would launch during Actavis's exclusivity period was worth tens of millions of dollars to Actavis: it was a large reverse payment. Shire's and Actavis's actions, which are unlawful and actionable under the federal antitrust laws, delayed generic competition for Intuniv from at least May 2013 through December 1, 2014, requiring purchasers to pay substantially higher prices.

19. This suit, brought under federal antitrust laws, seeks to recover the overcharges made by direct purchasers of Intuniv as a result of the defendants' unlawful and anticompetitive practices.

II. PARTIES

20. The plaintiff FWK Holdings, LLC is a limited liability company organized under the laws of the State of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Co., which, during the class period, as defined below, purchased brand Intuniv directly from Shire, and purchased generic Intuniv directly from Actavis, and suffered antitrust injury as a result of the anticompetitive conduct alleged herein.

21. The defendant Shire U.S., Inc. maintains its principal place of business and "US Operational Headquarters" at 300 Shire Way, Lexington, Massachusetts 02421. Shire's Lexington, Massachusetts facility is its largest facility and contains offices, labs, manufacturing, and warehousing capabilities. Shire maintains another facility in Cambridge, Massachusetts that contains manufacturing and warehousing facilities and offices. Throughout the class

period, Shire U.S., Inc. marketed and sold Intuniv in Massachusetts and elsewhere. Upon information and belief, Shire U.S., Inc. is the manufacturer and distributor of Intuniv.

22. The defendant Shire LLC is a Kentucky limited liability company with its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042. Shire LLC was a party to the anticompetitive reverse payment agreements at issue herein. Shire LLC develops, manufactures, and sells brand and generic pharmaceutical products in the United States, including Intuniv. Throughout the class period, Shire LLC marketed and sold Intuniv in Massachusetts and elsewhere.

23. The defendant Actavis Elizabeth LLC is a Delaware limited liability company. Actavis Elizabeth LLC developed, manufactured, marketed, and sold generic pharmaceutical products in the United States, including generic Intuniv. Actavis Elizabeth LLC holds ANDA No. 20-0881, the ANDA at issue in this case. Actavis Elizabeth LLC was a party to the anticompetitive reverse payment agreement at issue herein. During the class period, Actavis Elizabeth LLC conducted business in Massachusetts and elsewhere.

24. Actavis, Inc. was also a party to the anticompetitive reverse payment agreement at issue herein. In August 2016, Teva acquired the corporate parent of Actavis, Inc., Allergan plc. Upon that acquisition, Actavis, Inc. became Allergan Finance LLC.

25. The defendant Actavis Holdco US, Inc. is a Delaware corporation with its principal place of business in New Jersey. Upon information and belief, Allergan Finance LLC (f/k/a Actavis, Inc.), assigned its assets and liabilities to Actavis Holdco US, Inc. Upon information and belief, during the class period, Actavis Holdco US, Inc. and/or its predecessors in interest conducted business in Massachusetts and elsewhere.

26. The defendant Actavis LLC is a Delaware limited liability company with its principal place of business in New Jersey. Actavis LLC was a party to the anticompetitive

reverse payment agreement at issue herein. Actavis LLC develops, manufactures, markets, and sells generic pharmaceutical products in the United States. During the class period, Actavis LLC conducted business in Massachusetts and elsewhere.

27. All of the defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the defendants.

III. JURISDICTION AND VENUE

28. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by the plaintiff and members of the class resulting from the following: (i) the defendants' unlawful monopolization of Intuniv; and (ii) the defendants' conspiracy to restrain trade in the United States market for Intuniv and its generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1332(d) (class action), 28 U.S.C. § 1337(a) (antitrust), and 15 U.S.C. § 15 (Clayton Act).

29. Venue is appropriate within this district under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b) (general venue provision). The defendants transact business within this district, and the defendants transact their affairs and carry out interstate trade and commerce, in substantial part, in this district. Further, the defendants and/or their agents may be found in this district.

30. The defendants' conduct was within the flow of, and was intended to and did have a substantial effect on, interstate commerce of the United States, including in this district.

31. During the class period, Shire manufactured, sold, and shipped Intuniv in an uninterrupted flow of interstate commerce.

32. During the class period, each defendant, or one or more of each defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the conspiracy. The scheme in which the defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

33. The Court has personal jurisdiction over each defendant. Each defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

A. The Regulatory Structure for Approval of Brand and Generic Drugs

1. Approval of New Drugs and Their Associated Patents

34. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States. Under the FDCA, the manufacturer of a new drug must obtain FDA approval to sell the drug by submitting a New Drug Application (NDA). 21 U.S.C. § 355. An NDA must contain scientific data demonstrating that a drug is safe and effective. New drug applicants, however, are not required, and usually do not try, to show that their new drug product is superior to another similar, already approved, product.

35. The NDA must also identify any patents claimed to cover the new drug. 21 U.S.C. § 355(a), (b).

36. After FDA approval of an NDA, the brand drug's manufacturer may list any patents in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book"), that the brand manufacturer reasonably believes could be asserted against a generic manufacturer that manufactures, uses, or sells a generic version of the brand drug. 21 U.S.C. §§ 355(b)(1) & (c)(2).

37. The FDA relies solely on the brand manufacturer to provide an honest appraisal of its patent's (or patents') validity and applicability, as the FDA does not have the resources, expertise, or authority to analyze the manufacturer's patent(s). By listing patents in the Orange Book, the FDA is merely performing a ministerial act.

2. Approval of Generic Drugs under the Hatch-Waxman Amendments

38. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Amendments.

39. The Hatch-Waxman Amendments simplified the regulatory process for generic manufacturers. Previously, generic applicants had to follow the same steps as an applicant filing an NDA, including conducting costly and time-consuming clinical trials to establish safety and efficacy. This process delayed the approval of generic drugs, or deterred companies entirely from manufacturing generic drugs, and deprived drug purchasers of the benefit of generic competition.

40. Under the Hatch-Waxman Amendments, a manufacturer seeking approval to sell a generic version of a brand drug could file an ANDA. An ANDA relies on the scientific findings of safety and efficacy included in the brand manufacturer's NDA. The ANDA filer

need only show bioequivalence to the brand drug, and is not required to make an independent showing of safety or efficacy. Bioequivalence means that the generic product delivers substantially the same amount of active ingredient into a patient's blood stream for the same amount of time as does the corresponding brand drug and, therefore, has the same clinical effect.

41. The FDA assigns generic drugs that are therapeutically equivalent to their brand counterpart an "AB" rating. AB-rated drugs must (a) be bioequivalent to the brand drug, and (b) have the same formulation as the brand drug. For example, a tablet formulation cannot be AB-rated to a capsule formulation, even if it is bioequivalent to the capsule.

42. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products that contain identical amounts of the same active ingredients; have the same route of administration and dosage form; and meet applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and, therefore, may be substituted for one another. 21 U.S.C. § 355(j)(8)(B).

3. Paragraph IV Certification for a Generic Drug

43. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any valid patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. No patent for the brand drug has been filed with the FDA (a "paragraph I certification");

ii. The patent for the brand drug has expired (a "paragraph II certification");

iii. The patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "paragraph III certification"); or

iv. The patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

See 21 U.S.C. § 355(j)(2)(A)(vii).

44. A paragraph IV certification constitutes a constructive act of infringement, granting a brand drug manufacturer standing to sue the ANDA applicant. The brand manufacturer's right to sue is joined with the power to delay generic approval. If the brand manufacturer initiates a patent infringement action against the generic ANDA filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval of the ANDA until the earlier of (a) 30 months from the date of the notification, or (b) the issuance of a decision by a court that the patent for the brand drug is invalid or not infringed by the generic manufacturer's ANDA product. 21 U.S.C. § 355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant only "tentative approval" of the ANDA, even if the FDA determines that the ANDA would otherwise be ready for final approval. Thus, unless the generic manufacturer obtains a court order declaring the brand manufacturer's patent invalid or not infringed, the FDA cannot authorize the generic manufacturer to market its product until the 30-month period elapses.

45. As an incentive to generic drug manufacturers to seek early approval of generic alternatives to brand drugs, the first generic drug manufacturer to file an ANDA containing a paragraph IV certification typically receives a period of protection from competition from other generic versions of the drug approved through the ANDA process.

B. Characteristics of the Pharmaceutical Marketplace

46. The marketplace for the sale of prescription pharmaceutical products in the United States contains a unique and significant feature that can be exploited by a brand manufacturer to extend its monopoly over a particular product. In most industries and

marketplaces, the person who selects a product for purchase also pays for that product. Therefore, in most industries and marketplaces, the price of the product plays a predominant role in the person's choice of products and, consequently, manufacturers have a strong incentive to lower the price of their product to maintain profitability.

47. In the pharmaceutical marketplace, by contrast, there is a disconnect between product selection and payment. State laws require pharmacists to dispense only the drug that is prescribed to a patient by the patient's physician. Thus, the patient's physician chooses the product the patient will receive, with the patient (and in many cases the patient's insurer) only permitted to purchase and pay for the specific drug prescribed by the physician. A patient's (or insurer's) inability to obtain a drug without a prescription disconnects the product selection from the payment obligation.

48. Pharmaceutical manufacturers can exploit this disconnect. Brand manufacturers employ armies of sales representatives, known as "detailers," who descend upon physicians' offices to persuade physicians to prescribe their manufacturer's products. The detailers typically do not discuss the cost of the brand products with the physicians.

49. Physicians typically are not aware of the relative costs of brand pharmaceutical products, but even when physicians are aware of the relative cost, physicians are understandably insensitive to price differences because they do not pay for the products themselves. As a result, in the pharmaceutical marketplace, price plays an abnormally unimportant role in product selection.

50. Where two manufacturers each sell a drug that serves a similar therapeutic function, and each manufacturer uses a significant detailer force, the two similar drugs are often sold at very similar, high prices, eliminating any consumer benefit from that "competition." This circumstance, which includes two separate (and expensive) detailer forces, stands in stark

contrast to the circumstance in which the competitor is selling a bioequivalent generic without a detailer force. There, the generic price is significantly lower than the brand price, and purchasers benefit, as Congress intended by the Hatch-Waxman Amendments.

51. When the relative importance of the price difference between two brand pharmaceuticals (with no generic version available) is low, the price elasticity of demand – the extent to which sales go down when price goes up – is, by definition, also low. In turn, brand manufacturers have the ability to raise or maintain prices substantially above competitive levels, without losing sales. The ability to raise prices above competitive levels without losing sales is referred to by economists and antitrust courts as market power or monopoly power. Thus, the overall effect of the nature of the pharmaceutical industry and its marketing practices, described above, is often to allow brand manufacturers to gain and maintain monopoly pricing power, restrained only by competition from AB-rated generics.

52. Congress sought to address the prescription pharmaceutical market's disconnect from market forces, which results in anticompetitive prices for consumers, and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by providing incentives for the rapid development and sale of generics under the Hatch-Waxman Amendments.

53. States have addressed the disconnect by adopting drug product substitution laws that permit (or sometimes require) pharmacists to dispense AB-rated generic versions when the more expensive equivalent brand drug is prescribed, unless the physician specifically indicates "dispense as written," "brand medically necessary," or other similar language, or the patient specifically requests the brand drug. These laws reduce the impact of the pharmaceutical market's disconnect between product selection and payment by creating requirements or incentives to substitute the lower-priced generic for the brand drug at the pharmacy counter.

54. The congressionally-created incentives for generics, coupled with state substitution laws, prevent brand pharmaceutical manufacturers from exploiting the pharmaceutical marketplace disconnect between product selection and payment: the monopoly power of brand pharmaceutical manufacturers is limited to its lawful scope, and certain competitive pressures are restored to the pharmaceutical marketplace.

C. The Effect of Generic Drugs on Competition

55. As between bioequivalent generic drugs and their brand-name counterparts, the only basis for competition between generics, or between generics and the brand drug, is price.

56. Due to the price differences between brand and generic drugs, and other institutional features of the pharmaceutical industry (i.e., automatic substitution of the generic for the brand drug), the launch of a generic product results in the generic drug quickly taking over a large part of the brand drug's market.

57. Once a generic hits the market, it quickly erodes the sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months after launch, and 90% of the brand's unit drug sales after a single year. This competition results in dramatic savings for drug purchasers.

58. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to compete with and substitute for the brand drug. Therefore, without generic competition, the brand manufacturer can continue to profitably charge supra-competitive prices. However, the introduction of a generic drug results in a predictable and rapid loss of revenue for the brand drug seller. Moreover, once multiple generics have entered the market, total revenue for the manufacturer of the brand drug declines to a small fraction of the amount received prior to generic entry.

59. As a result, brand manufacturers, such as the defendants, view competition from generic drugs as a grave threat to their revenues and profit margins.

D. The Effect of Generic Drugs on Price

60. Typically, when there is a single generic competitor, such as an authorized generic, generics are 10-25% less expensive than their brand counterparts. This discount typically increases to between 50% and 80% (or more) when there are multiple generic competitors available. The FTC estimates that at the point one year after a generic enters the market, generic drugs sell on average at an 85% discount to the brand price. The Hatch-Waxman Act and state substitution laws drive this competition.

1. The First Generic ANDA Filer Receives a Period of Statutory, or de facto, Exclusivity

61. Generics may be classified as (i) first filer generics, (ii) later generic filers, and (iii) authorized generics.

62. To encourage manufacturers to seek approval of generic versions of brand drugs and challenge the validity and/or enforceability of patents or invent around patents, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer a 180-day period to market the generic version of the drug, free from competition from other ANDA filers. During this time, the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. That is, when a first filer generic files a substantially complete ANDA and certifies that the brand manufacturer's unexpired patents, listed in the Orange Book as covering the brand product, are either invalid or not infringed by the generic, the FDA cannot approve a later generic company's ANDA until that first filer generic has been on the market for 180 days (or until the first filer generic's exclusivity has been forfeited or relinquished). 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). This means the first approved generic drug is the only available ANDA-based generic drug for at

least six months, with the brand manufacturer permitted, but not required, to produce its own "authorized generic" during that 180-day time period. This permits the generic first filer to (a) monopolize the generic market or compete only with the brand manufacturer's authorized generic, and (b) charge a significantly higher generic price than would prevail if there were additional generics available to generate price competition.

63. As the Supreme Court recognized in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013), "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer generic.

64. First-filer generics that wait until all Orange Book-listed patents expire before marketing their product do not get the 180-day period of exclusivity to market their product without competition from other ANDA generics.

65. This 180-day window is referred to as the first-filer's six-month or 180-day exclusivity. The label, however, is a bit of a misnomer; while later ANDA filers must wait six months after the first filer generic's market entry to get final FDA approval, a brand manufacturer may market its own NDA-approved product as an "authorized" generic at any time.

2. The First AB-Rated Generic is priced below the Brand Drug

66. The value of first filer generic's 180-day exclusivity period is greatly diminished if the brand manufacturer launches an authorized generic.

67. Experience and economic research show that the first generic manufacturer to launch tends to price its product only slightly below the price of its branded counterpart. Because state substitution laws either require or permit the substitution of an AB-rated generic for a brand prescription, the first generic manufacturer often quickly captures a large market share, even with only a slight discount in price to the brand drug.

68. Thus, a significant portion of a first-filer generic's profit is regularly earned during the generic's exclusivity period.

69. When no other generic is on the market, the first filer prices its product in relation only to the brand product, which keeps the generic price much higher than when the first-filer generic faces competition from other generics. Because the brand company rarely drops the brand drug price to match the first-filer generic's price, the first-filer generic does not face the price competition present when additional generic products are available. Consequently, a first filer generic earns substantially greater sales and profits when there is no authorized generic (or later generic filers) on the market.

3. Later Generics Drive Prices Down Farther

70. When multiple generic competitors enter the market, price competition between the generic competitors drives prices down significantly. Multiple generic sellers typically compete vigorously over price, driving prices down toward marginal manufacturing costs.

71. According to the FDA and the FTC, the point of the greatest price reduction for pharmaceutical products is when the number of generic competitors goes from one to two. In that situation, there are two identical commodities that compete on price. Some typical estimates are that a single generic launch results in a near-term retail price reduction of 10%, but once there are two generics, near-term retail price reduction may reach 50%.

4. Authorized Generics, Like All Generics, Drive Prices Down

72. A brand manufacturer may sell a generic version of its brand drug, an "authorized generic," at any time. An authorized generic is chemically identical to the brand drug and is manufactured under the brand drug's NDA, but is sold as a generic product in a different package through either the brand manufacturer's generic subsidiary (if it has one) or through a third-party distributor.

73. Brand drug manufacturers facing competition from generics have large incentives to produce their own authorized generic in order to obtain some of the generic market. A study analyzing three examples of authorized generics found, "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[4]

74. For the brand manufacturer, launching an authorized generic during the generic first filer's 180-day exclusivity period provides a low-cost, low-risk means of retaining some of the market share, sales and revenue that its brand drug would otherwise lose to the generic first filer.

75. But first-filer generic manufacturers also have substantial incentives to avoid competition from an authorized generic. Studies have found that authorized generics both significantly lower the price of the generic drugs on the market and capture a significant amount of the first filer generic's market share.

76. Thus, competition from an authorized generic substantially reduces drug prices and the revenue of the first-filer generic; indeed, if the first-filer generic has regulatory or de facto exclusivity, an authorized generic can reduce the revenue of the first filer generic by more than half. Conversely, the absence of an authorized generic can more than double the first filer generic's revenue.

77. Freedom from an authorized generic during the initial 180-day exclusivity period is, thus, exceedingly valuable to the generic first filer.

[4] E.R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affairs 790, 796 (2007).

78. Thus, in exchange for the brand manufacturer's agreement not to produce an authorized generic, a generic manufacturer can benefit greatly by agreeing to delay its entry into the market (extending the brand drug's monopoly time period). With an agreement from a brand manufacturer to forebear launching an authorized generic, known as a "no-AG agreement," a generic manufacturer can be assured of selling into a closed market for generics during its exclusivity period, free of generic competition and the resulting price and revenue reductions.

79. The structure of the launch of an authorized generic takes into account provisions of the Medicaid Drug Rebate Program, a program that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients.

80. The program is authorized by Section 1927 of the Social Security Act. The program requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs. Manufacturers are then responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program

81. The amount of rebate due for each unit of a drug is based on statutory formulas. For example, for innovator drugs the rebate is the greater of 23.1 % of the Average Manufacturer Price (AMP) per unit or the difference between the AMP and the best price per unit (subject to CPI adjustments).

82. During the period applicable for this case, HHS regulations treated the pricing (for AMP and best price purposes) of authorized generics differently depending on whether the

authorized generic was sold by the NDA holder or a third party. The regulations defined an authorized generic as "any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FFDCA; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug." 42 C.F.R. § 447.506(a), as appearing in 43 FR 45253, Sept. 29, 1978; 72 FR 39239, July 17, 2007; 77 FR 29028, May 16, 2012 (effective: October 1, 2007 to March 31, 2016).

83. The regulations required that a "manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler." *Id.* at § 447.506(b).

84. The regulations further required that a "manufacturer holding title to the original NDA must include best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding title to the original NDA." *Id.* at § 447.506(c).

85. Given these limitations, common industry practice emerged to launch authorized generics through *bona fide* third party distributors, and not through the NDA holder. Doing so legitimately avoided the potential for the NDA holder to include the authorized generic sales in its AMP and best price calculations for its branded product sales.

86. The Medicaid program requirements, while impacting the *structure* of authorized generic arrangements, in no way undermine the basic *incentives and practices* of brand companies

to launch AGs; the practice and incentives remain vibrant, with the consequence that no-AG agreements work sweeping anticompetitive consequences.

E. Brand Manufacturers Can Employ Multiple Tactics to Block Generic Competition

87. Competition from lower-priced AB-rated generic drugs saves drug purchasers billions of dollars a year. These savings, however, result in lower profits for brand drug companies. Brand manufacturers thus seek to extend their monopolies for as long as possible.

1. Reverse Payments

88. In connection with the resolution of patent litigation arising out of paragraph IV certifications, brand manufacturers pay off generic competitors in exchange for delaying their entry into the market. These agreements not to compete are known as "reverse payment agreements." Brand and generic manufacturers execute reverse payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers.

89. In a typical reverse payment agreement, the brand manufacturer pays a generic manufacturer to (a) delay or abandon market entry, and (b) abandon the invalidity and unenforceability challenges to the brand manufacturer's patents. The brand manufacturer preserves its monopoly by paying some of its monopoly profits to the generic manufacturer, and the generic manufacturer agrees to delay marketing its product, allowing the brand manufacturer to have an extended monopoly period.

90. In the 1990s, these agreements took the form of cash payments from the brand manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class-action lawsuits, brand manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to hide the fundamentally anticompetitive character of these agreements and avoid liability.

91. In an increasing number of instances, brand manufacturers disguise the reverse payment to a first-filing generic manufacturer by including in the patent litigation settlement agreement a no-AG promise.

92. When a brand manufacturer agrees to a no-AG clause in exchange for delaying generic entry, the additional profits gained by causing delay to generic competition to achieve a longer monopoly period significantly outweigh any profit that could have been gained from selling an authorized generic. The bottom line is that the brand manufacturer gains a longer period of monopoly profits by delaying the onset of generic competition, and the generic first filer maintains higher generic sales and pricing during its 180-day exclusivity period. Thus, no-authorized generic agreements allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

93. Payment to the first filer in the form of no-AG promise is like a cash payment by the brand manufacturer to the first filer generic not to compete. But, this version of pay-for-delay through a no-AG agreement is even worse for purchasers than a naked cash payment. Without an AG and generic competition, the generic price remains high, and purchasers are overcharged twice: (1) during the period when the generic delays entry, allowing the brand manufacturer to continue its monopoly; and (2) when the generic enters the market but the price remains high because there is no competition from an AG.

94. Due to this double overcharge, courts have nearly universally found that no-AG promises violate the antitrust laws. As the First Circuit explained in considering a no-AG agreement, "antitrust scrutiny attaches not only to pure cash reverse payments, but to other forms of reverse payment that induce the generic to abandon a patent challenge, which unreasonably eliminates competition at the expense of consumers." *In re Loestrin 24 Fe Antitrust*

Litig., 814 F.3d 538, 550 (1st Cir. 2016); *see also In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone.") (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013)).

2. Bottlenecking the Generic Market

95. In many circumstances, a first-filer generic can help the brand manufacturer game the system by delaying not only its own market entry, but also the market entry of all other generic manufacturers. When the first filer agrees to delay marketing its generic drug, it also delays the start of the 180-day period of generic market exclusivity, sometimes referred to as "exclusivity parking." This tactic creates a bottleneck because later generic applicants cannot launch their generics until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

V. FACTS

A. Approval of Brand Intuniv and its related patents.

96. Intuniv is a prescription extended release tablet approved to treat attention-deficit/hyperactivity disorder (ADHD). The active ingredient in Intuniv, guanfacine hydrochloride ("guanfacine"), is not new, and was first marketed in 1986 under the brand name Tenex as a treatment for hypertension. By the time Intuniv was approved by the FDA in September 2009 for the treatment of ADHD, the active ingredient formulation of guanfacine had been off-patent and in the public domain for years.

97. While other drugs are available to treat the same or similar medical conditions, they are not AB-rated to Intuniv, cannot be automatically substituted for Intuniv by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Intuniv, and are not economic substitutes for, nor reasonably interchangeable with, Intuniv.

98. On September 2, 2009, the FDA approved Shire's NDA 022027, which sought to market extended-release guanfacine tablets in 1 mg, 2 mg, 3 mg and 4 mg dosages under the brand name Intuniv for the treatment of ADHD in children and adolescents.

99. Shire caused to be listed in the FDA Orange Book U.S. Patent Nos. 5,854,290 (the '290 patent), 6,287,599 (the '599 patent), and 6,811,794 (the '794 patent) as covering Intuniv 1-, 2-, 3-, and 4-mg tablets. Shire held an exclusive license to the '290 patent, and holds exclusive licenses to the '599 patent and the '794 patent. The '290 patent issued on December 29, 1998, from an application filed on September 21, 1995. If not for the dedication of the '290 patent to the public, discussed *infra*, it would have expired on September 21, 2015.

100. The '599 patent was filed on December 20, 2000. The '599 patent issued on September 11, 2001, and is set to expire on December 20, 2020.

101. The '794 patent was filed on December 20, 2001. The '794 patent was filed without relating to the earlier filed '599 patent (that is the '794 patent was not filed as a continuation, continuation-in-part, or divisional of the '599 patent). The '794 patent issued on November 2, 2004, and is set to expire on July 4, 2022.

102. The '290 patent is a method-of-use patent, and the '599 and '794 patents purport to cover the coating that enables the gradual release of the active ingredient, guanfacine hydrochloride. Formulation or method-of-use-patents can be easier to overturn than patents concerning the composition of matter of an active ingredient. Shire's strategy of focusing on new reformulations of off-patent active ingredients kept its development costs down, but made its patent portfolio weak.

103. Shire knew that the '290, '599, and '794 patents were weak and would more likely than not be invalidated if challenged, but listed the patents in the Orange Book to deter potential generic entrants. The '290 patent was so weak that the owners of the '290 patent who

granted Shire its exclusive license, and who were co-plaintiffs with Shire against Anchen, Actavis, and Teva, would later dedicate (surrender) it during patent litigation. The '290 patent was subsequently held invalid by an order dated July 23, 2012 in the *Shire v. Teva* litigation.

104. The Hatch-Waxman Act gave Shire a three-year exclusivity period on Intuniv, which expired on September 2, 2012. Until that date, Shire legally occupied 100% of the Intuniv market, charged supracompetitive prices, and earned monopoly profits.

105. Shire knew that when its three-year exclusivity period on Intuniv expired, (a) generic manufacturers would obtain FDA approval to market equivalent, but much less expensive, generic versions of the drug, (b) the vast majority of the market would go to those cheaper generics, and (c) Shire's monopoly on Intuniv, along with its supracompetitive profits, would disappear.

106. Facing the imminent and certain erosion of brand sales due to generic entry and substitution, Shire engaged in a scheme to block generic competition, employing a series of unlawful tactics.

B. Actavis' ANDA Threatened Shire's Weak Patents.

107. On December 29, 2009, generic drug manufacturer maker Actavis filed the first ANDA seeking FDA approval for generic Intuniv. Actavis's ANDA included a paragraph IV certification stating that all three of Shire's patents on Intuniv were either invalid or not infringed. As the first generic filer, Actavis was potentially entitled to 180 days free from competition from other generics (other than "authorized generics").

108. Following Actavis's ANDA, other generic manufacturers also filed ANDAs for Intuniv. Teva filed on January 25, 2010, Anchen filed on January 28, 2010 (and later transferred its ANDA to TWi), Mylan filed on November 30, 2010, and Sandoz filed on December 28, 2010. Impax and Watson also filed ANDAs.

109. Paragraph IV notice letters were sent to Shire by Teva on March 12, 2010, Actavis on April 2, 2010, and Anchen on April 23, 2010.

C. Shire Sues to Protect Its Franchise.

110. Shire filed paragraph IV litigation in the District of Delaware and elsewhere against the generic manufacturers, alleging infringement of the patents purportedly covering Intuniv. Shire sued Teva on April 22, 2010,[5] followed by Actavis on May 12, 2010[6] and Anchen on June 2, 2010.[7]

111. These lawsuits triggered 30-month stays of FDA approval for the generic companies' ANDAs: for Actavis, that meant no FDA approval until (i) the stay expired on October 5, 2012, or (ii) entry of a final judgment that the Intuniv patents were invalid, unenforceable, and/or not infringed. The FDA was also precluded from approving other generic Intuniv ANDAs (including Anchen's, Teva's, Mylan's and Sandoz's) due to 30-month stays.

112. Shire also asserted the Intuniv patents against other generic manufacturers in different courts: against Impax and Watson in the Northern District of California, and against Sandoz in the District of Colorado. Those cases settled before proceeding to any substantive dispositive motion briefing, both courts held *Markman* hearings on a few of the disputed claim terms. Neither claim construction order helped Shire overcome the transparent weaknesses in the Intuniv patents, and in at least the Northern District of California, Shire was thoroughly defeated at the *Markman* hearing, as evidenced by the fact that it moved for reconsideration of the judge's order. The motion was denied.

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[5] *Shire LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 10-329 (D. Del.)

[6] *Shire LLC, et al. v. Actavis Elizabeth LLC, et al.*, No. 10-397 (D. Del.)

[7] *Shire LLC, et al. v. Anchen Pharmaceuticals, Inc., et al.*, No. 10-484 (D. Del.)

113. On August 2, 2010, Shire's lawsuits against Actavis, Teva, and Anchen were consolidated under the Teva docket.

114. Prior to trial in Shire's lawsuit against Actavis, Teva, and Anchen, the parties briefed their respective positions on claim construction, and on March 22, 2012, the court conducted a Markman hearing, after which the court issued an opinion construing various limitations of the '290, '599, and '794 patents.

115. Independent claim 1 of the '599 patent claims "1. A pharmaceutical composition, comprising: (a) at least one pharmaceutically active agent that is pH dependent: (b) at least one non-pH dependent sustained release agent; and (c) at least one pH dependent agent that increases the rate of release of said at least one pharmaceutically active agent from the tablet at a pH in excess of 5.5." The rest of the claims of the '599 patent are dependent claims that further define those three elements of claim 1.

116. Independent claims 1 and 2 of the '794 patent are compositions including guanfacine and guanfacine hydrochloride, respectively. Independent claim 3 is a method of treating ADD and ADHD with three elements with similar definitions to the '599 patent's elements. Independent claim 8 is a method of reducing side effects associated with guanfacine by using three elements with similar definitions to the '599 patent's elements. The rest of the claims are dependent claims that further define claims 3 and 8.

117. In March 2012, just days before Shire would have to provide expert reports on the '290 patent in the consolidated litigation, Shire's co-plaintiffs dedicated the '290 patent to the public, effectively surrendering it. The documents that rendered the '290 patent invalid were continuously in Shire's and its co-plaintiffs' possession, and were produced in litigation in March 2011, a year before the patent was dedicated to the public.

118. Shire was expected to lose. Investment bank research analysts that followed the litigation held the belief that Shire would lose and expected that generics would enter the market as soon as the litigation concluded. In fact, BNP Paribas wrote in June 2012, "[w]e now adopt a bear scenario with Shire losing the litigation vs generic makers (17 Sept 2012) on the two remaining formulation patents ('599/'794) and the entry of generics in mid-2013 after a 6-9 month trial."

D. Shire Settles with Anchen/TWi.

119. On September 4, 2012, just two days after Shire's brand exclusivity period expired, Shire settled with TWi and Anchen. The settlement provided that (a) Anchen could launch a generic Intuniv on July 1, 2016, or earlier under certain circumstances, such as [redacted]

E. Absent the settlement, Shire would lose the patent litigation.

120. From September 17 through 20, 2012, a bench trial was held on Shire's claims against Actavis and Teva for infringement of the remaining two patents, the '599 and '794 patents. The court did not render a decision at that time.

121. At trial, the Actavis defendants presented compelling evidence that each asserted claim of the '599 patent and each asserted claim of the '794 patent was invalid as either anticipated or obvious in view of the prior art, including prior art not considered by the USPTO during prosecution of the '599 and '794 patents.

122. At trial, the generic defendants presented compelling evidence that claims 1, 4, 5, 8, 11-15 18, 20-23, 25 and 30 of the '599 patent were invalid as anticipated by one or more prior art references. In particular, these claims of the '599 patent were anticipated by either (1) European Patent Application 0266707 ("Sustained release labetalol tablet") ("EPA '707"), published May 11, 1988; (2) K.E. Gabr, "Effect of Organic Acids on the Release Patterns of Weakly Basic Drugs from Inert Sustained Release Matrix Tablets," 38(6) EUR. J. PHARM. BIOPHARM. 199 (1993) ("Gabr"); (3) K. Goracinova, et al., "pH Independent Controlled Release Matrix Tablets with Weakly Basic Drugs as Active Substances. Effect of Incorporated Acids," 14(1) BULL.CHEM. TECH. MACEDONIA 23 (1995) ("Goracinova"); and/or (4) International Application WO 99/66904 ("Incorporation of Latent Acid Solubilizing Agents in Coated Pellet Formulations to Obtain pH Independent Release"), published December 29, 1999 ("WO '904").

123. EPA '707, Gabr, and Goracinova were each published more than one year prior to the filing date of the '599 patent (and more than one year prior to the later filing date of the '794 patent) and qualify as prior art under then-applicable 35 U.S.C. §102(b). WO '904 was published almost one year before the filing date of the '599 patent and qualifies as prior art to the '599 patent under then-applicable 35 U.S.C. §102(a), and as prior art to the '794 patent under then-applicable 35 U.S.C. §102(b). The USPTO did not consider EPA '707, Gabr, Goracinova, and WO '904 during prosecution of the '599 or '794 patents.

124. At trial, the generics presented compelling evidence that each of the limitations of 1, 4, 5, 8, 11-15, 18, 20-23, 25 and 30 of the '599 patent were present either expressly or inherently in EPA '707, Gabr, Goracinova, and/or WO '904, thereby making the '599 patent invalid for anticipation.

125. Additionally, claim 6 of the '599 patent, which teaches guanfacine as an active ingredient, was shown to be invalid for obviousness. The generics presented compelling evidence at trial that prior art such as the '290 patent (dedicated to the public during the pendency of the *Shire v. Teva et al.* action) disclosed the use of guanfacine in an immediate release pharmaceutical formulation (such as the then-commercially available branded drug Tenex®, which had been an FDA-approved hypotensive agent for over two decades). Further, defendants presented compelling evidence that the prior art included the use of immediate release guanfacine pharmaceutical formulations to treat attention deficit disorders.

126. The generics also presented persuasive evidence that prior art sustained release formulations were used with pH-dependent drugs other than guanfacine (e.g. EPA '707).

127. Thus, the only differences between the prior art and claim 6 of the '599 patent are that (1) in the '290 patent, guanfacine is used in an immediate release pharmaceutical composition rather than sustained release, and (2) the prior art sustained release formulations were used with pH-dependent drugs other than guanfacine.

128. Additionally, claims 3 and 8 of the '794 patent, which teach the use of guanfacine to treat ADD and ADHD, and reducing side effects through sustained release, respectively, are likely invalid for obviousness. Prior to the filing of the '794 patent, Tenex was already recognized to be effective for treating ADHD. However, there were known side effects associated with such treatment, and clinicians were mitigating those side effects by splitting the dose into many smaller doses taken at different times in the day.

129. Prior to the filing of the '794 patent, it was also known that sustained release formulations were an effective strategy to solve problems of multiple dosing and side effects from single large doses.

130. Therefore, claim 6 of the '599 patent, which expressly recites guanfacine hydrochloride as an active ingredient, and claims 3 and 8 of the '794 patent, were more likely than not to be held invalid on the grounds that they would have been obvious to a person of ordinary skill in the art at the time of the alleged inventions under then-applicable 35 U.S.C. §103.

131. The generic defendants also presented substantial evidence that their ANDA products did not infringe Shire's patents.

132. Claim 1 of the '599 patent and claims 3 and 8 of the '794 patent, the only independent claims asserted in the litigation, all required the presence of at least one "pH dependent agent that increases the rate of release of said at least one pharmaceutically active agent from the tablet at a pH in excess of 5.5." During the patent litigation, this was referred to as "Element (c)." All Shire's other asserted claims were dependent on the independent claims, and therefore also implicitly included this limitation.

133. "If even one limitation is missing or not met as claimed, there is no literal infringement." *Elkay Mfg. v. Ebco Mfg.*, 192 F.3d 973, 980 (Fed. Cir. 1999). Actavis and Teva both asserted that, and presented persuasive evidence that, their formulations did not include Element (c).

134. Actavis presented compelling evidence that fumaric acid did not increase the rate of release of guanfacine from its generic Intuniv tablet more at a pH above 5.5 than below 5.5. Therefore, Actavis' formulation would probably not be considered to meet the requirements of Element (c).

135. Teva similarly presented persuasive evidence that fumaric acid did not increase the rate of release of guanfacine more at a pH above 5.5 than below 5.5, and therefore Teva's formulation would probably not be considered to meet the requirements of Element (c).

136. As an additional defense, Teva asserted that its formulation also did not infringe "Element (b)." Element (b) of the '599 and '794 patents required a "non-pH-dependent sustained-release agent." Teva presented persuasive evidence that the glyceryl behenate in its formulation functioned as a lubricant, not as a non-pH-dependent sustained release agent.

137. Therefore, Actavis and Teva's ANDA products more likely than not did not infringe the '599 and '794 patents, to the extent that those patents were valid.

138. Investment bank research analysts that followed the trial held the belief that Shire would lose, and expected that generics would enter the market as soon as the litigation concluded.

F. Shire enters into an anticompetitive settlement agreement with Actavis.

139. On October 5, 2012, the 30-month stay on Actavis's ANDA expired. On that same day, Actavis received final FDA approval of its ANDA. Because Actavis was the first filer for the product and had timely acquired approval, Actavis was guaranteed 180 days during which no other ANDA-approved generic manufacturer could launch its own generic Intuniv.

140. In early 2013, Actavis CEO Paul Bisaro stated that time was "of the essence" for a settlement with Shire, believing that a decision in the litigation in Actavis's favor was imminent, and if Actavis could settle before the decision came down, Shire would agree to terms highly advantageous to Actavis.

141. On April 25, 2013, Shire and Actavis settled their lawsuit before the Delaware District Court issued a ruling on the validity and/or infringement of Shire's patents. They memorialized their agreement in two documents: a "Settlement Agreement" and a "License Agreement." The Settlement Agreement expressly incorporated by reference the License Agreement. The parties executed these two agreements on the same day – indeed, the Settlement Agreement *required* contemporaneous execution.

142. The purported April 2013 "License Agreement" is in reality an anticompetitive reverse payment agreement.

143. Under the arrangement, Actavis is not given an immediate "license" to enter the market in April 2013 – instead, and although Actavis had final FDA approval to launch its generic Intuniv then and there, Actavis expressly agreed *to delay* entry of its ANDA-approved generic Intuniv for over a year and a half, until December 1, 2014.

144. In exchange, Shire agreed that, upon Actavis's eventual launch of a generic, [redacted] But this latter provision, given the economic and regulatory realities, was known to be a false possibility, rendering the agreement to function as a routine no-AG deal (with only the thinly veiled pretext intended to be used to avoid antitrust scrutiny).

145. Shire and Actavis knew the regulatory need of Shire to avoid Medicaid AMP and best price recalculations for its branded Intuniv sales that might well be required if Shire launched an authorized generic of Intuniv other than through a *bona fide* third party. And Shire had no captive subsidiary that could launch an authorized generic – it had always licensed that task to a third party, just as it had licensed the task of launching an authorized generic Intuniv to Anchen/TWi. Coupled with a purported "royalty" (discussed in the next paragraph), after entering into the reverse payment deal, Shire had little to no financial incentive to launch an in-house AG under the circumstances created by the reverse payment agreement; Shire had promised under the agreement not to allow a *bona fide* third party to do so, and had undermined the reasons to do so in-house through the agreement, and therefore the agreement functioned

as a classic no-AG agreement. (The incentives are also corroborated by what in fact happened. When Actavis eventually did launch its ANDA-approved generic in December 2014 after the period of delay, Shire did not launch an in-house AG (even though it ostensibly had a right to do so). The incentives created by the purported "license" agreement led it not to do so.

146. Shire and Actavis knew that Actavis's profits during the 180-day exclusivity period would be vastly increased in the absence of an authorized generic, so much so that it included an obligation of Actavis to pay back to Shire a 25% "royalty" on gross profits earned during the exclusive, no-AG period. The "royalty" added an incentive for Shire not to launch its own (i.e., non-third party) AG, yet ensured that Actavis would still make a significant additional profit, inducing it to enter into the deal and delay its generic entry. The arrangement resulted in (i) Shire maintaining its Intuniv monopoly, without generic competition, through December 1, 2014, and (ii) Actavis enjoying a 180-day exclusivity period during which it would not face competition from any other generic, including an authorized generic.

147. Shire's agreement with Anchen in September 2012, permitting Anchen to distribute a Shire authorized generic [redacted], caused Actavis to pursue settlement options with Shire instead of launching at risk in October 2012 or waiting for a favorable decision in the patent litigation to launch generic Intuniv, which would likely have occurred in May 2013. Even though Actavis knew that Shire's patents were weak, and would more likely than not be invalidated in the litigation, Actavis also knew that its profits during any 180-day generic exclusivity period would be vastly reduced if it had to compete with an authorized generic. Thus, Actavis chose to negotiate an agreement with Shire to be the sole generic at a later time rather than enter the market earlier and have to compete with the authorized generic from Anchen. Actavis's agreement with Shire, coupled with Shire amending

its agreement with Anchen to account for Actavis's exclusivity, ensured Anchen could not launch its authorized generic until after Actavis enjoyed 180 days of exclusivity.

148. Absent the no-AG promise, Anchen, at Shire's behest, would have launched an authorized generic during Actavis's 180-day exclusivity period, taking approximately 50% of Actavis's generic sales and substantially lowering the price that drug purchasers paid for generic Intuniv. Absent the no-AG promise, Actavis would not have agreed to delay its launch until December 1, 2014, and instead would likely have entered the market in or around May of 2013 at the latest, and possibly as early as October 2012.

149. When Shire settled with Actavis, the agreement was collusive and intended to maintain a monopoly and allocate the market: it enabled Shire to continue to receive monopoly profits until December 1, 2014 and enabled Actavis to control the generic market for 180 days thereafter, with Shire sharing in the Actavis generic's profits. The reverse payment agreement not only delayed Actavis's own entry into the market, it also created a bottleneck that blocked all other would-be generic Intuniv competitors by postponing the start (and thus also the conclusion) of Actavis's 180-day first-filer exclusivity period. Once Actavis's 180-day exclusivity period expired on June 2, 2015, Teva and Mylan launched their generic Intuniv products. TWi launched a generic Intuniv on June 3, 2015, and Sandoz launched a generic Intuniv on June 4, 2015.

G. The No-AG promise was a large reverse payment.

150. At this pre-discovery stage, the value of the reverse payment agreement to Shire and Actavis can be calculated using the known economics of the pharmaceutical industry.

151. Shire's sales of Intuniv were approximately $288 million in 2012, $335 million in 2013, and $327 million in 2014.

152. On the Shire side, Shire entered into the reverse payment agreement in April of 2013, and the agreement delayed generic entry until December 1, 2014, a period of about 19 months. Intuniv sales for the period ending June 2014 were $335 million. With generic entry, Shire would have lost about 80% of its sales; without generic entry, it kept those sales. As a result, by reason of the reverse payment agreement, Shire realized about $424.3 million in *additional* branded sales over this period ($335 million × 0.8 × 19/12). So by inducing Actavis to delay entry, Shire extended its monopoly period with Intuniv from at least May 1, 2013 through December 1, 2014, gaining almost one-half billion in additional sales.

153. On the Actavis side, a conservative calculation suggests the no-AG promise constituted a payment of approximately $52.7 million or more from Shire to Actavis.

154. Without generic competition of any kind (including AG competition now foreclosed by reason of the "license" agreement), Actavis would expect to capture 80% of unit sales and likely would have priced its generic product at about 90% of the brand's price. As a result, during its 180-day exclusivity without AG competition, Actavis would realize about $120.6 million in generic sales revenue ($335 million × 0.5 × 0.8 × 0.9). Only about 5% of Actavis's revenue would go to covering the minimal costs of manufacturing and selling its product, meaning that Actavis's net revenue during its six months of exclusivity would be about $114.6 million. After paying a royalty of 25% of its gross profits to Shire ($30.2 million, or 0.25 × 120.6 million), Actavis would earn about $84.5 million ($114.6 million – $30.2 million).

155. The value of the no-AG promise from Actavis's perspective is the difference between this $84.5 million figure and what Actavis would expect to earn if it launched with its approved ANDA product on or about May 2013 and faced competition from an Anchen-marketed authorized generic.

156. The authorized generic would take approximately 50% of unit sales from Actavis and drive down the price Actavis could command for its product. Generics would still take 80% of brand unit sales, but Actavis would split those sales about 50/50 with Anchen's AG product. Also, Actavis would have been able to charge only approximately half the brand price (because with two commodity products available, the price would drop steeply). So Actavis would gross only about $33.5 million during its 180-day period ($335 million × 0.5 × 0.8 × 0.5 × 0.5), and would realize a gross profit of about $31.8 million ($33.5 million × 0.95).

157. Since Actavis would earn about $84.5 million under the anticompetitive conditions, but only about $31.8 million under competitive ones, the net payoff to Actavis for its agreement to delay entry may fairly be estimated at this time at about $52.7 million.

158. If Actavis had launched under its own ANDA in May 2013, it would have triggered the commencement of its 180-day exclusivity and ensured competition from an authorized generic. Thus, while Actavis could expect profits in the first six months of about $36 million, it risked dramatically reduced profits thereafter, from both loss of market share and further price erosion due to entry by other generics. Here, there were four generic competitors in addition to Actavis that were poised to enter the market – and with five generics dividing the generics' 90% share of the market at substantially reduced prices, Actavis could expect only modest profits after the expiration of its 180-day exclusivity.

159. Actavis could not have obtained the approximately $52.7 million payment or its equivalent even if Actavis had won the patent litigation case against Shire. Shire made this payment in exchange for Actavis's agreement to delay generic competition to Intuniv. Absent Actavis's agreement to abandon its patent challenge and delay entry into the market with an ANDA-approved generic Intuniv, Shire would not have agreed to make the payment.

160. This $52.7 million figure is conservative: a floor, and not a ceiling, on the no-AG promise's value to Actavis. In fact, publicly-available information suggests that the incremental revenue that Shire paid to Actavis by the no-AG promise is even more than $52.7 million, and is at least $113 million. Shire disclosed in regulatory filings that it received $49.8 million in Intuniv royalty revenue from Actavis, which would mean Actavis earned $199.2 million in gross profits from sales of generic Intuniv during the first six months (because that $49.8 million represents 25% of Actavis's gross profits during its six-month exclusivity period). If Actavis earned at $199.2 million in sales revenues during the first six months, then, using the same calculations above, the no-AG promise was worth at least $107.6 million to Actavis.

161. This payment is large – it far exceeds the amount that Shire saved in litigation expenses by settling the patent case with Actavis. Studies have concluded that the median cost for an *entire* patent case with more than $25 million at stake is approximately $5.5 million.[8] Shire's future expected litigation costs at the time of the settlement with Actavis were minimal because, among other reasons, the patent case had already gone through trial and post-trial briefing at the time of the settlement.

162. The value of the reverse payment agreement to Shire is far greater even than the value to Actavis, because the more than 18-month delay in generic entry protected Shire's monopoly pricing over that time.

163. Shire's reverse payment to Actavis guaranteed two distinct periods of noncompetition: (a) the period before generic competition, from at least May 1, 2013 through December 1, 2014, whereby Shire and Actavis allocated 100% of the market to Shire; and (b) the 180-day exclusivity period after Actavis's entry, whereby Shire and Actavis allocated 100%

[8] *See King Drug. Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015); *see also* American Intellectual Property Law Association ("AIPLA"), *2011 Report of the Economic Survey – Median Cost of Patent Infringement Litigation.*

of generic sales to Actavis. So drug purchasers were overcharged twice: from at least May 2013 to December 2014, they were forced to pay overcharges for branded Intuniv, and during Actavis's exclusivity period, purchasers were forced to pay additional overcharges for generic Intuniv.

164. The defendants have no procompetitive explanation or justification for the reverse payment agreement.

165. Were it not for the agreement between Shire and Actavis, Actavis would likely have entered the market, at the latest, in May 2013 after prevailing in its patent litigation with Shire, leading to immediate competition with a Shire/Anchen authorized generic, and full competition with other generics by November 2013. Instead, Actavis did not release its generic until December 1, 2014, Shire remained off the generic market for the following six months, and generic entry by other manufacturers did not occur until June 2015.

166. Shire's and Actavis's actions were unlawful under the federal antitrust laws, and delayed generic competition for Intuniv from at least May 2013 through June 2, 2015, requiring consumers of the drug to pay substantially higher prices during that period.

VI. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO THE PLAINTIFF AND THE CLASS

167. Shire's sales of Intuniv were approximately $288 million in 2012, $335 million in 2013, and $327 million in 2014. These amounts total hundreds of millions of dollars more in sales than Shire would have achieved absent Shire's and Actavis's unlawful scheme to impair generic competition. Generic Intuniv products would have been priced at a fraction of the cost of brand Intuniv, and quickly captured most of the market for Intuniv.

168. Shire's and Actavis's overarching anticompetitive scheme impaired and delayed the sale of generic Intuniv in the United States and unlawfully enabled Shire to sell its Intuniv

at artificially inflated prices. But for Shire's unlawful conduct, generic competitors would have been able to compete, unimpeded, with their own generic versions of Intuniv, at a much earlier date.

169. But for the defendants' anticompetitive conduct, as alleged above, Shire/Anchen and Actavis would have both sold a generic Intuniv as early as October 2012 or, at the latest, after a decision in the patent case in May 2013, and entry of multiple other generic manufacturers would have come six months later.

170. Were it not for the defendants' anticompetitive conduct, the plaintiff and other members of the class would have: (1) purchased lower-priced generic Intuniv, instead of the higher-priced brand Intuniv, during the period when Actavis delayed its entry to the market; and (2) paid a lower price for generic Intuniv products during Actavis's 180-day exclusivity period.

171. As a consequence, the plaintiff and other direct purchasers have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

VII. MARKET POWER AND MARKET DEFINITION

172. Prior to December 1, 2014, Shire had monopoly power in the market for Intuniv because it had the power to exclude competition and/or raise or maintain the price of Intuniv at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable. From December 1, 2014 through June 1, 2015, Shire and Actavis had substantial market power in the market for Intuniv and its generic equivalent, because they had the power to exclude competition and/or raise or maintain the price of brand (Shire) and generic (Actavis) Intuniv at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

173. Prior to June 1, 2015, a small but significant, non-transitory increase to the price of brand Intuniv would not have caused a significant loss of sales. From December 1, 2014 through June 1, 2015, a small but significant, non-transitory increase in the price of generic Intuniv would not have caused a significant loss of sales.

174. Brand Intuniv does not exhibit significant, positive cross-elasticity of demand with respect to price with any other guanfacine product or treatment for ADHD other than AB-rated generic versions of Intuniv.

175. Brand Intuniv is differentiated from all other guanfacine products, and all other ADHD treatments, other than the AB-rated generic versions of brand Intuniv.

176. Shire and Actavis needed to control only brand Intuniv and its AB-rated generic equivalents, and no other products, in order to maintain the price of Intuniv profitably at supra-competitive prices. Only the market entry of competing, AB-rated generic versions would render the defendants unable to profitably maintain their prices for Intuniv without losing substantial sales.

177. Shire sold brand Intuniv and Actavis sold generic Intuniv, during the 180-day exclusion period, at prices well in excess of marginal costs and in excess of the competitive price, and, therefore, Shire and Actavis enjoyed high profit margins.

178. The defendants have had, and exercised, the power to exclude generic competition to brand Intuniv.

179. The defendants, at all material times, enjoyed high barriers to entry with respect to brand and generic Intuniv.

180. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the defendants' ability to control the price of Intuniv and generic Intuniv, and to exclude relevant competitors, without the need to show the relevant antitrust

markets. The direct evidence consists of, *inter alia*, the following facts: (a) generic Intuniv would have entered the market at a much earlier date, at a substantial discount to brand Intuniv, but for defendants' anticompetitive conduct; (b) gross margins were at all times substantial; and (c) the defendants never lowered the price of Intuniv in response to the pricing of other brand or generic drugs.

181. To the extent proof of monopoly power by defining a relevant product market is required, the plaintiff alleges that the relevant antitrust market is the market for Intuniv and its AB-rated generic equivalents.

182. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

183. Shire's market share in the relevant market was 100% until December 1, 2014, after which Shire and Actavis collectively had 100% market share in the relevant market until June 2, 2015, when Teva and Mylan launched generic Intuniv.

VIII. MARKET EFFECTS

184. The defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. The defendants designed a scheme to delay competition on the products' merits, to further Shire's anticompetitive purpose of forestalling generic competition against Intuniv, in which Actavis cooperated in order to increase its own profits. The defendants carried out the scheme with the anticompetitive effect of maintaining supra-competitive prices for the relevant product.

185. The defendants implemented the scheme as described herein. These acts, in combination and individually, were undertaken to serve the Defendants' anticompetitive goals.

186. The defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Intuniv, and later

Actavis's generic Intuniv, from competition. These actions allowed the Defendants to maintain a monopoly and exclude competition in the market for Intuniv and its AB-rated generic equivalents, to the detriment of the plaintiff and all other members of the direct purchaser class.

187. The defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Shire and Actavis to sell Intuniv without generic competition. Were it not for the defendants' illegal conduct, one or more generic versions of Intuniv would have entered the market sooner, and Actavis's generic would have faced competition during its 180-day exclusivity period from a Shire authorized generic.

188. By way of example, and not limitation, in the absence of the defendants' conduct: (i) Actavis would have launched its generic Intuniv at risk possibly as early as October 2012, and no later than May 2013 after the conclusion of its patent litigation with Shire; (ii) Shire/Anchen would have launched an authorized generic to compete with Actavis's generic; and (iii) six months after Actavis's launch, in April 2013 (assuming an October 2012 launch by Actavis) or November 2013 (assuming a May 2013 launch by Actavis), there would have been full competition from many other generic manufacturers, resulting in a much cheaper generic Intuniv. Instead, full competition did not actually occur until June 2015.

189. The defendants' illegal acts and conspiracy to delay generic competition for Intuniv caused the plaintiff and all members of the class to pay more than they would have paid for Intuniv absent this illegal conduct.

190. Typically, generic versions of brand drugs are priced significantly below the brand counterpart. As a result, upon generic entry, direct purchasers substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and the brand drug, continues to lose even

more market share to the generics. This price competition enables all direct purchasers of the drug to purchase generic versions at a substantially lower price, and/or purchase the brand drug at a reduced price. Consequently, brand drug manufacturers have a keen financial interest in delaying the onset of generic competition.

191. Generic companies holding first-to-file exclusivity likewise have a keen financial interest in delaying their entry into the market in exchange for maintaining generic exclusivity, and a share of the monopoly profits that their delay makes possible. Additionally, purchasers experience substantial cost inflation from these delays.

192. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as the plaintiff and members of the class, would have paid less for Intuniv by (a) paying lower prices on their remaining brand purchases of Intuniv, (b) substituting purchases of less-expensive generic Intuniv for their purchases of more-expensive brand Intuniv, and/or (c) purchasing generic Intuniv at lower prices sooner.

193. Thus, the defendants' unlawful conduct deprived the plaintiff and members of the class of the benefits from the competition that the antitrust laws are designed to ensure.

IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

194. During the relevant time period, the defendants sold Intuniv across state lines.

195. During the relevant time period, the plaintiff and members of the class purchased substantial amounts of Intuniv and/or generic Intuniv directly from the defendants. As a result of the defendants' illegal conduct, the plaintiff and the members of the class were compelled to pay, and did pay, artificially inflated prices for Intuniv and generic Intuniv.

196. During the relevant time period, the defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign

travel, and interstate and foreign wire commerce. All the defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

X. CLASS ACTION ALLEGATIONS

197. The plaintiff bring this action on behalf of themselves and all others similarly situated under Federal Rules of Civil Procedure 23(a) and 23(b)(3):

> All persons or entities in the United States and its territories, or subsets thereof, that purchased Intuniv and/or generic Intuniv in any form directly from Shire or Actavis, including any predecessor or successor of Shire or Actavis, from October 5, 2012 until the effects of the defendants' conduct ceased (the "class").

198. Excluded from the class are Shire, Actavis, and any of their officers, directors, management, employees, subsidiaries, and affiliates.

199. Members of the direct purchaser class are so numerous and geographically dispersed that joinder of all members is impracticable. The plaintiff believes that the class is numerous and widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The class is readily identifiable from information and records in the defendants' possession.

200. The plaintiff's claims are typical of the claims of the members of the class. The plaintiff and all members of the direct purchaser class were damaged by the same wrongful conduct of the defendants – *i.e.*, as a result of the defendants' conduct, they paid artificially inflated prices for Intuniv and any available AB-rated generic equivalents.

201. The plaintiff will fairly and adequately protect and represent the interests of the class. The interests of the plaintiff are coincident with, and not antagonistic to, those of the other members of the class.

202. Counsel that represent the plaintiff are experienced in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigations involving pharmaceutical products.

203. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members, because the defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

204. Questions of law and fact common to the class include:

a. Whether the defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b. Whether there exist any legitimate procompetitive reasons for some or all of the defendants' conduct;

c. To the extent such justifications exist, whether there were less restrictive means of achieving them;

d. Whether direct proof of the defendants' monopoly power is available and, if so, whether it is sufficient to prove the defendants' monopoly power without the need to define the relevant market;

e. Whether the defendants' scheme, in whole or in part, has substantially affected interstate commerce;

f. Whether the defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiff and the members of the class;

g. Whether Shire and Actavis conspired to delay generic competition for Intuniv;

h. Whether, pursuant to the reverse payment agreement, Shire's promise not to compete against Actavis's generic product constituted a payment;

i. Whether Shire's agreement with Actavis was necessary to yield some cognizable, non-pretextual procompetitive benefit;

j. Whether Shire's compensation to Actavis was large and unexplained;

k. Whether the reverse payment agreement created a bottleneck to further delay generic competition for Actavis;

l. Whether the reverse payment harmed competition;

m. Whether, prior to December 1, 2014, Shire possessed the ability to control prices and/or exclude competition for Intuniv;

n. Whether, from December 1, 2014 through June 1, 2015, Shire and Actavis possessed the ability to control prices and/or exclude competition for Intuniv;

o. Whether the defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Intuniv;

p. Determination of a reasonable estimate of the amount of delay the defendants' unlawful monopolistic conduct caused, and;

q. The quantum of overcharges paid by the class in the aggregate.

205. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to

prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

206. The plaintiff knows of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

COUNT ONE – CONSPIRACY IN RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. § 1)

(Against All Defendants)

207. The plaintiff hereby repeats and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

208. On or about April 25, 2013, Shire and Actavis entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Shire paid Actavis substantial consideration in exchange for Actavis's agreement to delay bringing its generic version of Intuniv to the market, the purpose and effect of which were to: (a) delay generic entry of Intuniv in order to lengthen the period in which Shire's brand Intuniv could monopolize the market and make supracompetitive profits; (b) keep Shire's authorized generic off the market during Actavis's 180-day generic exclusivity period, thereby allowing Actavis to monopolize the generic market for Intuniv during that period, and allowing Actavis to make supracompetitive profits, which were shared with Shire; and (c) raise and maintain the prices that the plaintiff would pay for Intuniv at supracompetitive levels until June 2015.

209. This reverse payment agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

210. Shire and Actavis are liable for this reverse payment agreement under a "rule of reason" standard under the antitrust laws.

211. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

212. As a direct and proximate result of Shire's and Actavis's anticompetitive conduct including the reverse payment, as alleged herein, the plaintiff was harmed.

COUNT TWO – MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)
(Against Shire)

213. The plaintiff hereby repeats and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

214. Until December 1, 2014, Shire possessed monopoly power in the relevant market and possessed the power to raise and maintain supracompetitive prices and/or exclude competitors from the relevant market.

215. Shire engaged in an exclusionary conduct scheme that involved paying Actavis to abandon its patent challenge and to agree to delay its generic entry.

216. The goal, purpose, and/or effect of Shire's scheme was to maintain and extend its monopoly power with respect to Intuniv. Shire's illegal scheme to delay the introduction of generic Intuniv allowed it to continue charging supra-competitive prices for Intuniv without a substantial loss of sales.

217. If Shire had not arranged for other manufacturers of generic Intuniv, besides Actavis, to be prevented from entering the market until June 1, 2015, and had competed with Actavis's generic by selling an authorized generic, the plaintiff and other members of the class would have purchased lower-priced generic Intuniv, and/or would have received lower prices on some or all of their remaining brand purchases, at earlier periods of time and in far greater quantities.

218. As a result of Shire's illegal scheme, the plaintiff and the class paid more than they would have paid for Intuniv, absent the illegal conduct. But for the illegal conduct, competitors would have begun marketing generic versions of Intuniv at a far earlier date, resulting in cost savings to the plaintiff and other direct purchasers.

219. During the relevant period, the plaintiff and the class purchased substantial amounts of Intuniv directly from Shire. As a result of Shire's illegal conduct, the plaintiff and the members of the class were compelled to pay, and did pay, artificially inflated prices for Intuniv. The plaintiff and all class members paid prices for Intuniv that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic Intuniv instead of the more expensive brand Intuniv; and/or (b) the price of brand Intuniv and generic Intuniv were artificially inflated by Shire's illegal conduct.

220. The anticompetitive consequences of Shire's actions far outweigh any arguable procompetitive benefits. Shire acquired and extended a monopoly through unlawful means.

221. Shire's scheme was, in the aggregate, an act of monopolization undertaken with the specific intent to monopolize the market for Intuniv and generic Intuniv in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

XII. DEMAND FOR JUDGMENT

WHEREFORE, the plaintiff, on behalf of itself and the proposed class, respectfully demand that this Court:

a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the class, and declare the plaintiff as the representative of the class;

b. Enter joint and several judgments against the defendants and in favor of the plaintiff and the class;

c. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

d. Award the plaintiff and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, the plaintiff, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Dated: March 10, 2017

Respectfully submitted,

/s/ Thomas M. Sobol

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, certify that, on this date, the foregoing document was served by filing it on the court's CM/ECF system, which will automatically send a notification of such filing to all counsel of record via electronic mail.

Dated: February 9, 2018

/s/ Thomas M. Sobol
Thomas M. Sobol